



Attorney's Docket No. 06275-160002 / D 1863-1P US

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Ann-Kristin Karlsson et al.      Art Unit : 1623  
Serial No. : 09/993,669      Examiner : Leigh C. Maier  
Filed : November 27, 2001  
Title : STERILE POWDERS, FORMULATIONS AND METHODS OF PRODUCING  
THE SAME

**BOX AF**

Commissioner for Patents  
Washington, D.C. 20231

AMENDMENT

In response to the action mailed September 9, 2002 ("Office Action"), Applicants submit the following remarks. Please note that the following amendments (i) **raise no new issues that will require further consideration or search** and (ii) **only more clearly demarcate the scope of the claims so as to place them in condition for allowance without touching the merits of the application within the meaning of 37 C.F.R. § 1.116(b).**

OK to  
enter  
LCM  
12-20-02

In the claims:

Please delete claim 55 without prejudice.

Please amend claim 3, 8, 10, 11 and 39 as follows:

Sub 1  
~~3. (Amended) A pharmaceutically acceptable inhalation powder in the form of finely divided particles having a mass median diameter (MMD) of less than 10  $\mu$ m, said particles being heat sterilized and comprising a glucocorticosteroid or ester, acetal, or salt thereof, wherein the glucocorticosteroid or ester, acetal, or salt thereof, comprises an asymmetric acetal structure.--~~

Sub 2  
~~8. (Amended) A sterile pharmaceutical suspension comprising an aqueous suspension of a pharmaceutically acceptable inhalation powder in the form of finely divided particles, said particles being heat sterilized and comprising a glucocorticosteroid or ester, acetal, or salt thereof, wherein the glucocorticosteroid or ester, acetal, or salt thereof, comprises an asymmetric acetal structure, and wherein at least 80% of the particles have a mass median diameter (MMD) of less than 10  $\mu$ m.~~